IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. Enter case number 5:23-mc-00019-RJ

AZURITY PHARMACEUTICALS, INC.)
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v.)
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BIONPHARMA INC., ET AL)
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NON-PARTY QHP CAPITAL GP, LLP'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO QUASH SUBPOENA TO TESTIFY AND PRODUCE DOCUMENTS AT A DEPOSITION IN A CIVIL ACTION PENDING IN DELAWARE

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Pursuant to Rules 26 and 45 of the Federal Rules of Civil Procedure (the "Federal Rules"), Nonparty QHP Capital GP, LLP ("QHP") hereby submits this Memorandum of Law in Support of Motion to Quash the Subpoena to Testify and Produce Documents issued by BionPharma Inc. ("Bion") to QHP on May 22, 2023. In support of this Motion, QHP states the following:

I. INTRODUCTION

Nonparty QHP moves to quash the subpoena seeking the appearance at a deposition of a representative of QHP and the production of documents at the law offices of Ellis & Winters LLP, 4131 Parklake Avenue, Suite 400, Raleigh, N.C. 27612. The subpoena was issued in the case *Azurity Pharmaceuticals, Inc. v. Bionpharma Inc.* 21-cv-1286 pending in the District of Delaware (the "QHP Subpoena," attached hereto as **Exhibit A**). The QHP Subpoena imposes an undue burden on QHP, which requires the Court to quash or modify the subpoena pursuant to Federal Rule 45(d)(3)(A). The QHP Subpoena also seeks the disclosure of QHP's confidential commercial information, which permits the Court to quash or modify the subpoena pursuant to Federal Rule 45(d)(3)(B).

II. STATEMENT OF FACTS

A. Litigations Between and Among Azurity, Bion and CoreRx.[1]

Bion issued the QHP Subpoena in the District of Delaware patent infringement cases between Plaintiff, Azurity Pharmaceuticals, Inc. ("Azurity) and defendant Bion. (*Azurity v. Bion*, Case Nos. 21-cv-1286 consolidated with 21-cv-1455, the "Delaware Patent Cases") The Delaware

[1] QHP provides the following litigation history to assist the Court in understanding why the discovery sought by Bion from nonparty QHP is improper, and therefore why the Court should quash Bion's subpoena. There are numerous citations in this Memorandum to filings in the Southern District of New York and the District of Delaware. Counsel for QHP understands that the Court has access to these voluminous materials through PACER, but counsel is certainly willing to file those materials here if that is preferable to the Court.

Patent Cases involve Azurity's brand product EPANED, an oral liquid formulation of a blood pressure medication called enalapril. (Delaware Patent Cases, Judge Goldberg's Memorandum Opinion [ECF 255 p. 2]) Azurity filed nine patent applications for enalapril liquid from March 2016 to April 2021. (*Id.*) In August 2018, Bion filed an abbreviated new drug application ("ANDA") with the Food and Drug Administration ("FDA") for a generic oral enalapril liquid. (*Id.* p. 3) Azurity argues that Bion's generic enalapril violates its patents. Bion states that it made alterations to its generic enalapril to design around Azurity's patents. (*Id.*) Azurity has filed seven lawsuits regarding Bion's generic enalapril, five against Bion and two against Bion's contract manufacturer, CoreRx Inc. ("CoreRx"). (ECF 255 p. 3-4) The litigating parties refer to these groups of patent lawsuits as the "First Wave," "Second Wave," and "Third Wave." (*Id.* p. 4) The Delaware Patent Cases are referred to as the Third Wave cases and were consolidated in the District of Delaware on March 2, 2022 before Judge Goldberg from the Eastern District of Pennsylvania, sitting by designation in the District of Delaware. (*Id.* p. 5)

In the Delaware Patent Cases, Azurity claims that Bion infringed its patents by producing generic enalapril. Bion denies that it infringed Azurity's patents. Bion brought antitrust counterclaims in the Third Wave patent suits. The counterclaims allege that Azurity sought to maintain a monopoly in generic enalapril by filing lawsuits against Bion. (*Id.*) Bion also claims that Azurity brought the First Wave patent lawsuits to obtain the 30-month stay that applies in Hatch-Waxman litigation even though Azurity did not expect to prevail on the merits. Azurity denies these allegations and maintains that it brought the patent lawsuits in good faith to protect its patents.

Azurity sought to dismiss Bion's antitrust claims alleging, among other things: (1) Bion could not show antitrust injury because Azurity's lawsuits failed to keep Bion's generic product

off the market; (2) the Azurity lawsuits did not cause delay in the entry of Bionpharma's generic enalapril to market; (3) the Azurity lawsuits were not objectively baseless (requiring detailed analysis of the patents at issue in the First Wave suits, and differences in the formulations of the First Wave and Third Wave patents); and (4) the Azurity lawsuits were not subjectively baseless – e.g., in that Bion has not shown that Azurity brought the lawsuits to thwart competition. The Court denied Azurity's Motion to Dismiss and allowed Bion's antitrust counterclaims to proceed. (Delaware Patent Cases ECF 255 p. 19).

In November 2020, at a time in which Bion had an ownership interest in CoreRx, Bion entered into the Master Manufacturing and Supply Agreement (the "MMSA") with CoreRx under which CoreRx agreed to manufacture and supply Bion with generic enalapril. (*Bion v. CoreRx* 21 cv 10656 S.D.N.Y. [ECF 183 p. 102-103]) Bion and its private equity parent, Signet Healthcare Partners ("Signet") owned an interest in CoreRx until January 2021. (*Id.*) In January 2021, Signet sold a portion of its interest in CoreRx to NovaQuest Capital Management LLP ("NovaQuest") (*Id.*) NovaQuest is also an investor in Azurity, a fact known to Signet and Bion at the time of the sale of a portion of Signet's interest in CoreRx to NovaQuest. (*Id.*) QHP is the successor in interest to NovaQuest.

Azurity sued CoreRx twice in different courts for infringing Azurity's patents by manufacturing generic enalapril for Bion (the "CoreRx Suits"). Bion alleged that CoreRx and Azurity were not genuinely adverse parties in the CoreRx Suits because NovaQuest was the parent to both Azurity and CoreRx. (ECF 255 p. 6) Azurity and CoreRx settled the CoreRx Suits pursuant to the Litigation Settlement Agreement (the "Azurity-CoreRx LSA"). The Azurity-CoreRx LSA required CoreRx to stop supplying Bion with generic enalapril.

Bion sued CoreRx in the Southern District of New York alleging that CoreRx breached the MMSA by refusing to supply Bion with generic enalapril under that contract (the "SDNY Lawsuit" [ECF 1]). Azurity produced documents as a third party in the SDNY Lawsuit including organizational charts with information about its relationship with QHP, communications with CoreRx on the topic of Azurity's Enalapril patents, Epaned, the Azurity-CoreRx LSA, and the MMSA.[2] CoreRx, a party to the SDNY Lawsuit, produced documents to Bion in that litigation that included many of the same documents and topics that Bion seeks from QHP in the QHP Subpoena, including communications between QHP and CoreRx on the topic of Azurity's Enalapril patents and Epaned, the Azurity-CoreRx LSA, and the MMSA.[3] Bion and CoreRx settled the SDNY Lawsuit on or about May 15, 2023. (*Bion v. CoreRx* 21 cv 10656 S.D.N.Y. "SDNY Lawsuit" [ECF 243])

B. The QHP Subpoena Deposition Topics and Document Requests.

The QHP Subpoena seeks testimony on the following topics:

1. The organizational structure of, and corporate relationships between and among, and any agreements between and among Azurity, Novaquest, QHP, and CoreRx.

2. The reasons for QHP's acquisition of CoreRx and the facts and circumstances surrounding that acquisition.

3. QHP's knowledge of and involvement with the CoreRx Suits, the Azurity-CoreRx LSA, and the MMSA.

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[2] (Delaware Patent Cases [ECF 339 p. 2] ("Azurity has produced organizational charts detailing its structure and relationship with its private equity sponsor Novaquest, communications with CoreRx concerning the [CoreRx Suits] litigation and negotiation of the [Azurity-CoreRx LSA] settlement, competition with Epaned and relevant markets, advertising, and data.")))

[3] (*Id.* fn. 2 (As explained regarding the communications referenced in footnote 2 supra: "Bionpharma obtained most of the interparty communications from CoreRx itself in the [SDNY Lawsuit] since CoreRx was a party there and Azurity was not.")))

4. Communications between QHP and Azurity relating to Bionpharma, Bionpharma's ANDA Product, the CoreRx Suits, the MMSA, or any actual or potential competition to Epaned.

5. Communications between QHP and CoreRx relating to Bionpharma, Bionpharma's ANDA Product, the CoreRx Suits, the MMSA, or actual or potential competition to Epaned.

6. The level of control and/or oversight QHP exercises over Azurity.

7. The level of control and/or oversight QHP exercises over CoreRx.

8. The existence and location of documents, including and communications regarding each of the above-listed Topics.

9. The identity of the individuals who have knowledge of each of the above-listed Topics.

(**Exhibit A**, attached hereto).

The QHP Subpoena also includes Document Requests for the following documents to be produced by the witness at the deposition:

Request No. 1. Documents sufficient to show the ownership of QHP, Azurity, and CoreRx.

Request No. 2. Documents sufficient to show organizational structure of, and corporate relationship between and among QHP, Azurity, and CoreRx.

Request No. 3. All documents and things concerning relationships, agreements, and communications between QHP and Azurity or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to the Enalapril Liquid Patents, Related Patent Applications, Epaned, and/or NDA No. 208686.

Request No. 4. All documents and communications relating to Bionpharma, Bionpharma's ANDA Product, or any actual or potential competition to Epaned.

Request No. 5. All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, the MMSA, the Azurity-CoreRx LSA, and/or any other enalapril ANDA filer.

Request No. 6. All documents and things relating to QHP's decisions, negotiation, or agreement to take an ownership interest in CoreRx.

> **Request No. 7.** All documents, communications, and things relating to the CoreRx Suits, Azurity's decision to institute the CoreRx Suits, and/or QHP's knowledge or involvement with the CoreRx Suits or Azurity's decision to institute the CoreRx Suits.

(*Id.*)

C. In the SDNY Lawsuit, Bion Sought and Received from Azurity and CoreRx Nearly Identical Information to the Information it is Now Seeking in the QHP Subpoena.

Bion has been in search of support for its theory about alleged collusion among Azurity, CoreRx, and NovaQuest/QHP since at least November 2022 in the SDNY Lawsuit. Bion sought and obtained discovery in the SDNY Lawsuit from both CoreRx as a party and Azurity as a nonparty. In November 2022, in the SDNY Lawsuit, Bion moved to compel production of communications between Azurity and CoreRx on the topic of the Azurity-CoreRx LSA and the patents at issue in the Delaware litigation. (SDNY Lawsuit [ECF 181 p. 1, citing ECF 164, 167]) In addition, Bion sought the depositions of CoreRx directors Frank Leo and Ashton Poole who were both affiliated with QHP. (*Id.*) Bion's counsel alleged that it needed the documents and testimony to support its theory that the CoreRx Suits and Azurity-CoreRx LSA were a sham based on the fact that NovaQuest owned an interest in both Azurity and CoreRx. (*Id.* p. 2, citing ECF 175 at 2) The Court ordered CoreRx to produce communications between CoreRx and Azurity, and, as a result, Bion agreed not to pursue the Leo and Poole depositions. (*Id.*)

CoreRx produced over 16,000 documents. (*Id.*) None supported Bion's collusion theory that the CoreRx Suits or Azurity-CoreRx LSA were a sham. (*Id.*) CoreRx's CEO Ajay Damani testified at a deposition on January 18, 2023. (SDNY Lawsuit [ECF 181-4 p. 2) Damani testified that he learned of the Azurity suit against CoreRx after it was filed, (*Id.* p. 3) that he consulted with either Verne Davenport or Jeff Edwards of QHP after he received notice of Azurity's lawsuit

against CoreRx (*Id.* p. 4) and was told that QHP (then part of NovaQuest) did not "get involved in matters relating to our portfolio companies; they operate independently and act independently" (*Id.*) and that Damani should "figure this out on [his] own." (*Id.* p. 9) Damani further testified that in consultation with his legal counsel, he decided to enter the Azurity-CoreRx LSA and did so without input from the CoreRx Board. (*Id. p. 7*)

Bion also sought and obtained discovery from Azurity in the Delaware Patent Cases in the attempt to support its collusion theory. Indeed, Bion's First Set of Requests for the Production of Documents and Things ("Bion's Document Requests") in the Delaware Patent Cases calls for many of the same topics and documents requested in the QHP Subpoena. (Delaware Patent Cases [ECF 157]) Specifically, Bion's Document Requests seek:

- Documents sufficient to show the ownership interest of NovaQuest[4] in Azurity and CoreRx. (ECF 157-1 p. 8 Bion Document Requests ¶11);
- Documents sufficient to show organizational structure of, and corporate relationship between Azurity, NovaQuest and CoreRx." (*Id.* p. 8 Bion Document Requests ¶12);
- Documents sufficient to show the ownership of Azurity, NovaQuest, and CoreRx. (*Id.* p. 8 Bion Document Requests ¶13);
- All documents and things concerning relationships, agreements, and communications between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof) as they relate to the Enalapril Liquid Patents, Related Patent Applications, Epaned, and/or NDA No. 208686. (*Id.* p. 8 Bion Document Requests ¶14);
- Any settlement agreements between Azurity and either NovaQuest or CoreRx or both (or any affiliate or subsidiary thereof)…[related to Enalapril patents]. (*Id.* p. 8 Bion Document Requests ¶15);
- All documents and things concerning the Azurity-CoreRx LSA, including any drafts of the Azurity-CoreRx LSA. (*Id.* p. 9 Bion Document Requests ¶20);
- All documents and communications with NovaQuest relating to Bionpharma, Bionpharma ANDA Product, or any actual or potential competitor to Epaned. (*Id.* p. 9 Bion Document Requests ¶22);

[4] While the Bion Document Requests continually refer to NovaQuest rather than QHP, QHP is NovaQuest's successor in interest.

- All documents and communications with NovaQuest relating to CoreRx's relationship with Bionpharma, including documents and communications pertaining to the MMSA. (*Id.* p. 9 Bion Document Requests ¶23);

- All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member past or present, of CoreRx, including Messrs Nailesh Bhatt, Vern Davenport, Jeff Edwards, and Frank Leo. (*Id.* p. 10 Bion Document Requests ¶25);

- All documents and communications relating to generic competition to Epaned, the Enalapril Liquid Patents, Bionpharma ANDA Product, CoreRx, the Azurity-CoreRx LSA, NovaQuest, and any other ANDA filer, to or from any board member past or present, of Azurity, including Messrs Nailesh Bhatt, Vern Davenport, Jeff Edwards, and Frank Leo. (*Id.* p. 10 Bion Document Requests ¶26);

- All documents and things, including communications between Azurity and NovaQuest, relating to NovaQuest's decision, negotiation, or agreement to take an ownership interest in CoreRx. (*Id.* p. 10 Bion Document Requests ¶27);

- All documents, communications, and things between Azurity and NovaQuest relating to Azurity's decision to sue CoreRx for the alleged infringement of the Third Wave Patents. (*Id.* p. 10 Bion Document Requests ¶29)

Bion's First Set of Interrogatories in the Delaware Patent Cases requested:

- Describe in detail the relationship between Azurity, NovaQuest, and CoreRx, including any ownership interest that NovaQuest has in Azurity and/or CoreRx and the extent of such ownership interest. (*Id.* Bion First Set of Interrogatories p. 22 ¶4])

Azurity has made substantial document productions in response to the Bion Document Requests. According to a Declaration filed in the Delaware Patent Cases by Azurity counsel Jeff Banks, Azurity has already produced discovery relevant to Bion's antitrust counterclaims consisting of over 6,000 documents of over 120,000 pages. (Delaware Patent Cases [ECF 290 ¶ 2]) Azurity's document production included documents relevant to the CoreRx Suits. (*Id.* ¶ 5)

In addition to ongoing document discovery in the Delaware Patent Cases, Bion previously issued a non-party Rule 45 deposition to Azurity in the SDNY Lawsuit (the "Azurity Subpoena")[5] (SDNY Lawsuit [ECF 183 p. 11-18]). The Azurity Subpoena is attached hereto as **Exhibit B**.

As is true with the Bion Document Requests, which seek many of the same materials Bion now requests in the QHP Subpoena, many of the collusion-theory topics on which Bion obtained discovery from Azurity in the SDNY Lawsuit are included in the QHP Subpoena. Both the QHP Subpoena and the Azurity Subpoena reference communications among Azurity, CoreRx, and Novaquest/QHP[6] on the topic of the MMSA. (**Exhibit A**, p. 7 (Schedule A), Topic No. 3; **Exhibit B** (handwritten p. 6), Topic No. 1) Both the QHP Subpoena and the Azurity Subpoena reference communications among Azurity, CoreRx, and Novaquest/QHP on the topic of the CoreRx Suits. (**Exhibit A**, p. 8 (Schedule A), Topic Nos. 4 and 5; **Exhibit B** (handwritten p. 6), Topic No. 2) Both the QHP Subpoena and the Azurity Subpoena reference communications among Azurity, CoreRx, and Novaquest/QHP on the topic of the Azurity-CoreRx LSA. (**Exhibit A**, pp. 7-8 (Schedule A), Topic Nos. 3 and 8; **Exhibit B** (handwritten pp. 6-7), Topic Nos. 5 and 6) And both the QHP Subpoena and the Azurity Subpoena reference communications among Azurity, CoreRx, and Novaquest/QHP on the topic of the Azurity patents. (**Exhibit A**, p. 8 (Schedule A), Topic Nos. 4 and 5; **Exhibit B** (handwritten p. 7), Topic No. 9)

Azurity did not object to Bion's nonparty subpoena for deposition testimony in the SDNY Lawsuit. Instead, Azurity offered the testimony of Mr. Amit Patel, Azurity's Executive Chairman and former CEO, as a witness with knowledge on all of the topics in the Bion subpoena. Based on

[5] The Azurity Subpoena was filed as one of numerous exhibits to a letter to the Court from Bion counsel.

[6] The Azurity Subpoena was directed to NovaQuest and the QHP Subpoena is directed to QHP. As explained above, QHP is the successor in interest to NovaQuest.

a letter to the Court from Azurity counsel, Mr. Patel's deposition was scheduled in the SDNY Lawsuit for April 20, 2023, with an agreement that Bion would ask Mr. Patel about issues in common between the SDNY Lawsuit and the Delaware Patent Cases. (SDNY Lawsuit [ECF 214]) Mr. Patel's deposition is not publicly available. Based on the content of the Azurity Subpoena, however, Bion had an opportunity to question Mr. Patel about all of the topics in the Azurity Subpoena including the same topics that overlap with those in the QHP Subpoena.

Mr. Patel's position that there was no collusion among QHP, Azurity, and CoreRx has long been clear. On February 2, 2022, before the Azurity Subpoena, Mr. Patel submitted a Declaration in the SDNY Lawsuit. (SDNY Lawsuit [ECF 90]) In his Declaration, Mr. Patel specifically addressed and denied the validity of Bion's speculation about alleged collusion among Azurity, CoreRx, and NovaQuest in connection with the CoreRx Suits and/or the Azurity-CoreRx LSA. Mr. Patel testified:

> I understand that Bionpharma has speculated that NovaQuest Management LLC "NovaQuest" participated in strategy related to Azurity's litigations against CoreRx and the settlement thereof. That is not true. NovaQuest was not involved in Azurity's decision to initiate litigation against CoreRx and took no position on whether the companies pursued or reached settlement. Moreover, Bionpharma has speculated that CoreRx and Azurity are somehow working in collusion to protect one another's interests. This is absolutely false – both parties are only looking towards their own interests.

(*Id.* ¶ 12) On information and belief, at his deposition in the SDNY Lawsuit, Mr. Patel testified consistently with his Declaration. Bion was a party to the SDNY Lawsuit and has access to the Patel deposition testimony in that case.

D. The SDNY Court Denied Bion's Request to Depose Two CoreRx Directors Because Bion Produced No Evidence to Support its Collusion Theory.

Despite the fact that neither the 16,000 CoreRx documents nor the testimony of CoreRx CEO Damani provided any support for Bion's collusion theory, (SDNY Lawsuit [ECF 181 p. 2]),

Bion sent deposition notices on January 22, 2023, five days after Damani's deposition, seeking the depositions of Mr. Davenport and Mr. Edwards as directors of CoreRx. (*Id.*) Bion sought information from Mr. Davenport and Mr. Edwards regarding: (1) the circumstances of the Azurity-CoreRx LSA; and (2) purported collusion between Azurity and CoreRx in the CoreRx Suits or Azurity-CoreRx LSA. (*Id.*)

Counsel for CoreRx opposed the depositions and sought a protective order from the court. In support of its position, CoreRx filed a letter with the court attaching declarations of both Mr. Davenport and Mr. Edwards. (SDNY Lawsuit [ECF 181 Ex. B and C]) The declarations establish: (1) neither knew about any lawsuit filed by Azurity against CoreRx prior to the suit being filed; (2) neither was involved in CoreRx's decision to settle with Azurity; (3) neither discussed settlement between CoreRx and Azurity with anyone prior to the entry of settlement; (4) neither knew that Azurity and CoreRx planned to enter a settlement agreement before they entered into the agreement; (5) neither has been involved in the daily management of CoreRx; and (6) neither made any decision about whether CoreRx should stop manufacturing and selling generic enalapril to Bion. (*Id.*) The Edwards and Davenport declarations further establish that Mr. Edwards and Mr. Davenport informed Mr. Damani that they should not be involved in decisions about the lawsuits filed against CoreRx by Azurity because they were affiliated with both entities. (SDNY Lawsuit [ECF 181 p. 2, Ex. B and C])

On February 23, 2023, the Court in the SDNY Lawsuit held a hearing as to whether the Court should grant CoreRx's motion for a protective order barring the depositions of Mr. Edwards and Mr. Davenport. (SDNY Lawsuit [ECF 192 p. 1]) The Court agreed with CoreRx and granted the protective order, stating; "I don't believe that Bionpharma has shown that either Davenport or

Edwards would have any relevant knowledge, yet alone unique knowledge with regard to the [Azurity/CoreRx] negotiations." (*Id.* p. 14-15)

III. LEGAL STANDARD

Rule 45(d)(3)(A) of the Federal Rules of Civil Procedure provides that on "timely motion" in the district where compliance with a subpoena is required (here, the Eastern District of North Carolina), the Court "must" quash or modify a subpoena that: (iv) subjects a person to undue burden." Fed. R. Civ. P. 45(d)(3)(A). Rule 45(d)(3)(B) provides that the court in the district where compliance with a subpoena is required "may" quash or modify a subpoena if it requires: (i) disclosing a trade secret or other confidential research, development, or commercial information…." Fed. R. Civ. P. 45(d)(3)(B).

The Fourth Circuit has cautioned that courts should exercise special care in analyzing the enforceability of subpoenas issued to nonparties to litigation. *Virginia Dept. of Corr. v. Jordan*, 921 F.3d 180, 189 (4th Cir. 2019) ("Courts must give the recipient nonparty status 'special weight' leading to an even more 'demanding and sensitive' inquiry than one governing discovery generally.") (quoting *In re Public Offering PLE Antitrust Litig.*, 427 F.3d 49, 53 (1st Cir. 2005)). In affirming the district court's order denying the 30(b)(6) corporate representative deposition of a nonparty, the Court in *Jordan* stated:

> Nonparties faced with civil discovery requests deserve special solicitude. They should not be drawn into the parties' dispute unless the need to include them outweighs the burdens of doing so, considering their non-party status. This undue-burden analysis must be conducted based on concrete facts and issues in the litigation, not on vague generalities or speculation.

Id. at 194. In order to enforce a nonparty subpoena, the requesting party "should be able to explain why it cannot obtain the same information or comparable information that would also satisfy its needs from one of the parties to the litigation — or, in the appropriate case, from other third parties that would be more logical targets for the subpoena." *Id.* at 189; *see also Schaaf v. Smith Kline*

Beecham Corp., 233 F.R.D. 451 (E.D.N.C. 2005) ("In the context of evaluating subpoenas issued to third parties, a court will give extra consideration to the objections of a non-party, non-fact witness in weighing burdensomeness versus relevance.") (quotations omitted)).

Rejecting the argument that the existence of a protective order in the case justified forcing a nonparty to divulge information implicating privacy or confidentiality concerns, the Court in *Jordan* observed:

> As courts have recognized, sometimes even the most rigorous efforts of the recipient of [sensitive] information to preserve confidentiality in compliance with the provisions of such a protective order may not prevent inadvertent compromise. [I]t is very difficult for the human mind to compartmentalize and selectively suppress information once learned, no matter how well-intentioned the effort may be to do so.

921 F.3d at 193 (citations and quotations omitted).

IV. ARGUMENT

A. The Court Should Quash the QHP Subpoena Because It Constitutes an Undue Burden on QHP.

Rule 45 requires a court to quash or modify a subpoena if it imposes an undue burden. *See* Fed. R. Civ. P. 45(d)(3)(A)(iv). The QHP Subpoena imposes an undue burden on QHP in terms of the time and money it would require in order to comply with the subpoena. Moreover, that burden is greatly magnified by the absence of a factual record in the SDNY Lawsuit to support the collusion theory that is at the heart of Bion's subpoena to QHP. In the SDNY Lawsuit, as described in Subsection II.C. above, Bion has already received extensive documentary and testimonial evidence from Azurity and CoreRx on the same issues identified in the QHP Subpoena. That information does not support Bion's collusion theory. The breadth of the QHP Subpoena, covering eight litigations over five years, dictates that the burden of conducting the investigation needed to comply with the QHP Subpoena would be enormous. Considering the special care and the

demanding and sensitive inquiry that courts must apply when discovery is sought from nonparties to a lawsuit, the Court should quash the QHP Subpoena.

1. The QHP Subpoena is not Proportional to the Needs of the Delaware Patent Cases Insofar as it Seeks Extensive Discovery from Nonparty QHP.

Under Rule 26, the scope of discovery must be:

> . . . proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.

See Fed. R. Civ. P. 26(b)(1). Here, Bion seeks to impose a time-consuming and massive expense on nonparty QHP, even though Bion already has "access to relevant information" from the parties to the Delaware Patent Cases. Even a cursory review of the Definitions and Deposition Topics and Document Requests in the QHP Subpoena (Exhibit A hereto) reveals the magnitude of the information sought by the subpoena.

The principal focus of the deposition portion of the QHP Subpoena is to seek testimony on the topics of QHP's knowledge of or communications among QHP, CoreRx, and/or Azurity about: (1) the CoreRx Suits; (2) the Azurity-CoreRx LAS; and (3) the MMSA. (**Exhibit A**, pp. 7-8 (Schedule A), Topic Nos. 3-5, and 8). The Document Request portion of the QHP Subpoena is even broader, seeking all documents concerning communications among QHP, Azurity, and CoreRx related to: (1) Azurity's patents for enalapril; (2) Azurity patents related to enalapril; (3) Azurity's related patent applications; and (4) Azurity's New Drug Application for Epaned. (**Exhibit A**, p. 7 (Schedule B), Request Nos. 3, 4, 5, and 7) It also seeks documents and communications related to: (1) Bion's ANDA product; (2) any actual or potential competition to Epaned; (3) generic competition to Epaned; (4) the Enalapril Liquid Patents; (5) the MMSA; (6) the Azurity-CoreRx LSA; and (7) any other enalapril ANDA filer. (*Id.*)

Bion's expansive requests for all documents relating to all of Azurity's patents and to Bion's ANDA product would require an overwhelming investigative effort given the extensive litigation history surrounding the patents. The nine patent applications that are the subject of the QHP Subpoena were filed between March 2016 and April 2021. (Delaware Patent Cases [ECF 255 p. 2]) Bion filed its ANDA for generic enalapril in August 2018. (*Id.*) Azurity has filed five lawsuits challenging Bion's generic enalapril liquid. (*Id.*) These litigations include: (1) A Delaware case, 18CV1962, filed in December 2018 with a last entry date of September 2022 consisting of 333 docket entries; (2) A Delaware case, 19CV1067, filed in June 2019 with a last entry date of September 2022 consisting of 320 docket entries; (3) A Delaware case, 20CV1256, filed in September 2020 with a last entry date of September 2022 consisting of 112 docket entries; (4) Ongoing Delaware and New Jersey cases, 21CV1286 and 21CV1455, consolidated in Delaware as the Delaware Patent Cases filed in June 2021 consisting of 339 docket entries as of June 9, 2023.

Another topic covered by the QHP Subpoena are the CoreRx Suits. CoreRx filed the CoreRx Suits against Azurity in connection with CoreRx supplying Bion with generic enalapril. Azurity filed one of the CoreRx Suits in Florida in October 2021, 21CV2515, with a last entry date of March 2022, consisting of 50 entries and the second CoreRx Suit in Delaware in October 2021, 21CV1522, with a last entry date of November 2021, consisting of seven entries.

The QHP Subpoena requests all documents and communications relating to the MMSA, a significant November 2020 agreement between Bion and CoreRx that was heavily litigated. The SDNY Lawsuit consisted of 243 docket entries and was settled on May 15, 2023. (SDNY Lawsuit [ECF 243])

The length, breadth, and number of litigations involved in the various patent and contract disputes between and among Azurity, CoreRx, and Bion dictate that the QHP Subpoena seeks an enormous investigation into at least five years of active overlapping litigations, which would impose a significant burden on QHP.

2. Bion Cannot Articulate Any Benefit that Would Justify the Significant Burden Imposed on QHP as a Nonparty.

Parties may not obtain discovery when the burden and expense outweighs its likely benefit. *See* Fed. R. Civ. P. 26(b)(1). This limitation in Rule 26(b)(1) is even more of an imperative where the person or entity from whom a party seeks discovery is a nonparty to the litigation.

Here, Bion cannot establish that the QHP Subpoena would benefit Bion. The QHP Subpoena appears to be nothing more than another attempt by Bion to test its baseless theory that Azurity, CoreRx, and QHP colluded in connection with the MMNA, the CoreRx Suits, and/or the Azurity-CoreRx LSA. CoreRx challenged the factual basis of Bion's collusion theory at the February 23, 2023, hearing in the SDNY Lawsuit, and the Court found that Bion's theory lacked merit. (SDNY Lawsuit [ECF 192 p. 14-15]) Bion provided zero factual support for its collusion theory and, as a result, the Court issued a protective order barring the depositions of Vern Davenport and Jeff Edwards.[7] (*Id.*) The discovery sought by the QHP Subpoena is therefore all-the-more disproportional to the needs of the Delaware Patent Cases when a prior court has found that the theory upon which the discovery is based lacks enough merit to justify further discovery.

Furthermore, it is not merely the case that Bion has offered no support for its collusion theory that would justify the issuance of demanding testimony and documents from nonparty QHP.

[7] Notably, although Mr. Davenport and Mr. Edwards are affiliated with QHP, their depositions were sought in the SDNY Lawsuit as *parties* to the litigation based on their status as Board Members of CoreRx. The case against allowing Bion to subpoena QHP for deposition testimony is even stronger here, because QHP is subpoenaed as a nonparty to the Delaware Patent Cases.

Rather, the evidence submitted in the SDNY Lawsuit actually *refuted* Bion's collusion theory. As discussed in Subsections II.C. and D. above, every witness who provided testimony or a statement in the SDNY Lawsuit stated that there was no collusion among Azurity, CoreRx, or QHP (NovaQuest) with respect to the MMNA, the CoreRx Suits, the Azurity-CoreRx LSA, or any other matter. Azurity's Executive Chairman, Amit Patel submitted a Declaration in the SDNY Lawsuit stating that there was no collusion among Azurity, CoreRx, and QHP/Novaquest and, on information and belief, provided consistent deposition testimony on the same topic. CoreRx CEO Ajay Damani testified in the SDNY Lawsuit that there was no collusion between Azurity, CoreRx, and QHP (then NovaQuest). Declarations submitted by Jeff Edwards and Vern Davenport in the SDNY Lawsuit confirmed that there was no such collusion. (SDNY Lawsuit [ECF 181 p. 2, Ex. B and C])

Notwithstanding that Bion asked for and received access to 16,000 documents from CoreRx in the SDNY Lawsuit, based on review of the transcript of the hearing which was available on the public docket for the SDNY Lawsuit, Bion did not rely on a single one of those documents in support of its collusion theory in its unsuccessful bid before that court to take the depositions of Mr. Davenport and Mr. Edwards. (SDNY Lawsuit ECF 192) Bion is not just seeking deposition testimony and documents from a nonparty, then, it is seeking discovery from a nonparty when the well-developed factual record in the SDNY Lawsuit refutes its basis for such discovery. Bion should not be permitted to ignore the discovery it received in the SDNY Lawsuit, or be permitted to perform an "end run" around the rulings by the court in that litigation. *Cf. Saxon Innovations, LLC v. Nokia Corp.*, 6:07-cv-490, 2009 WL 10677277, *4 (E.D. Tex., Oct. 30, 2009) (refusing to allow an "end run" around the court's protective order, and holding that "[plaintiff] has failed to

adequately explain why [a nonparty's] confidential information is necessary given the production [plaintiff] has obtained from the Remaining Defendants.").

3. Even if Bion Could Articulate Some Reason, Contrary to the Facts of the SDNY Lawsuit, that it Should Again be Allowed to Pursue its Discredited Collusion Theory, Bion Should do so with Azurity and CoreRx – Not QHP.

As discussed above, not only can Bion articulate no facts on which to base its collusion theory, the facts developed in the SDNY Lawsuit on the same topics as those requested in the QHP Subpoena refute Bion's collusion theory. Bion has received 16,000 documents from CoreRx on the topic of its collusion theory in the SDNY Lawsuit. It has also received a substantial production from Azurity as a nonparty to the SDNY Lawsuit on the collusion theory. Bion also has received over 120,000 pages of documents from Azurity in the Delaware Patent Cases relevant to its antitrust counterclaim, including information about the CoreRx Suits. (Delaware Patent Cases [ECF 290, ¶¶ 2 and 5]) Azurity and CoreRx executives have also provided declarations and/or deposition testimony refuting Bion's collusion theory. The fact that Bion is now pursuing the same collusion theory with the QHP Subpoena suggests that it wants to conduct a fishing expedition of a nonparty – a tactic prohibited in connection with nonparty discovery, and even disfavored as to parties.

It seems reasonable to conclude that, by now, Bion has had ample opportunity to find support for its collusion theory through prior discovery. And to the extent it needs more, it should seek such discovery from the parties in the Delaware Patent Cases. QHP, as a nonparty to the Delaware Patent Cases, is not the correct party from which to seek that additional discovery. Azurity and CoreRx could not have colluded with QHP without Azurity and/or CoreRx participating in that theoretical collusion. CoreRx was a party to the recently settled SDNY Lawsuit, and CoreRx provided substantial discovery to Bion on the topics Bion now seeks to

explore in the QHP Subpoena. Azurity is a party to the Delaware Patent Cases in which the QHP Subpoena was issued, and Azurity has recently provided Bion with 120,000 pages of discovery on the same or similar topics. (Delaware Patent Cases [ECF 290, ¶ 2 and 5])

Bion is currently seeking information from Azurity, a party in the Delaware Patent Cases, on its collusion-theory topic. As discussed in Section II.C. above, the Bion Document Requests seek identical information as the information Bion now requests from nonparty QHP in the QHP Subpoena. Based on recent docket entries in the Delaware Patent Cases, it seems that Bion and Azurity are in the middle of a dispute as to whether Azurity has or has not fully complied with the Bion Document Requests. In a June 1, 2023 filing, Bion complained that Azurity had not fully produced documents including those related to Bion's collusion theory. (Delaware Patent Cases [ECF 321]) For its part, Azurity has complained that Bion refuses to produce depositions, hearing transcripts, exhibits, and expert reports from the SDNY Lawsuit, which Azurity claims undermine Bion's collusion theory. (Delaware Patent Cases [ECF 333]) Most recently on June 9, 2023, Azurity took issue with Bion's complaint about missing collusion-theory documents, stating; "Apparently unhappy with the lack of evidence supporting its allegations, Bionpharma is attempting to wish into existence materials that are simply not there…." (Delaware Patent Cases [ECF 339 p. 2]) Azurity affirmatively represented to the court: "Azurity has either produced documents or confirmed that no responsive documents exist." (*Id.*)

Based on the information that emerged from the SDNY Lawsuit, it appears that Azurity is correct that Bion has had ample discovery on the collusion issue and that Bion is simply unhappy with the facts. Regardless of how the court or the parties resolve the discovery dispute between Bion and Azurity in the Delaware Patent Cases, one thing is certain – it is wholly inappropriate for

Bion to seek the same information from nonparty QHP about which it is currently fighting with party Azurity in the Delaware Patent Cases.

Similarly inappropriate is Bion's attempt to seek deposition testimony from QHP on the same topics on which Bion seeks, but has not yet obtained, deposition testimony from party Azurity. Bion's March 14, 2023, Rule 30(b)(6) subpoena to Azurity (Delaware Patent Cases [ECF 286]) requested some of the identical information Bion now seeks from nonparty QHP. Specifically, paragraph 50 of the Rule 30(b)(6) subpoena to Azurity seeks: "The organizational structure of, and corporate relationship between, Azurity, NovaQuest, and CoreRx." (*Id.* p. 22) Paragraph 51 seeks: "Azurity's knowledge of NovaQuest's acquisition of CoreRx and the facts and circumstances surrounding that acquisition. (*Id.*) Paragraph 52 seeks: "The indemnity granted by Azurity to CoreRx in the… [Azurity-CoreRx LSA]. (*Id.*) Paragraph 53 seeks: "Communications with NovaQuest relating to Bionpharma, Bionpharma's ANDA product, the CoreRx Suits, and any actual or potential competition to Epaned. (*Id.*) Paragraph 55 seeks: "Azurity's decisions to institute and dismiss the CoreRx Suits." (*Id.*)

Bion has also noticed the deposition of Azurity's Executive Chairman, Amit Patel, in the Delaware Patent Cases. On information and belief, Bion has not yet scheduled Mr. Patel's deposition. The Court in the SDNY Lawsuit ordered that the testimony Mr. Patel had already provided in the SDNY Lawsuit was to be used in both the SDNY Lawsuit and the Delaware Patent Cases. (SDNY Lawsuit [ECF 186]) Allowing the deposition requested in the QHP Subpoena to proceed would mean that nonparty QHP would be providing testimony in advance of the Azurity 30(b)(6) witness and Azurity's Executive Chairman. This is precisely the type of improper third-party discovery that Rule 45 was designed to prevent.

If Bion is to be further indulged with any additional discovery on its failed collusion theory, beyond the voluminous discovery it has already obtained from Azurity and CoreRx, it should be from Azurity in the Delaware Patent Cases and/or from materials previously produced by CoreRx in the SDNY Lawsuit As the Fourth Circuit in *Jordan* explained, the party issuing a nonparty subpoena "should be able to explain why it cannot obtain the same information or comparable information that would also satisfy its needs from one of the parties to the litigation – or, in the appropriate case, from other third parties that would be more logical targets for the subpoena." 921 F.3d at 189. Bion can provide no explanation as to why it must seek testimony and documents from QHP in advance of exhausting either document or testimonial discovery from party Azurity – neither of which Bion has done at present. The Court therefore should quash the QHP Subpoena pursuant to the undue burden prong of Rule 45(d)(3)(A).

4. The Court Should Quash the QHP Subpoena Because It Seeks Disclosure of Confidential Commercial Information.

In addition to seeking information about communications among CoreRx, Azurity, and QHP in connection with the lengthy and complex litigation history among Bion, CoreRx, and Azurity, Bion seeks both testimony and documents consisting of QHP's confidential research, development, or commercial information. These requests serve as an independent reason for the Court to quash the subpoena. *See* Fed. R. Civ. P. 45(d)(3)(B)(i).

Specifically, deposition Topic 1 seeks testimony about the "organizational structure of, and corporate relationship between and among and any agreements between and among Azurity, NovaQuest, QHP, and CoreRx." (**Exhibit A** p. 7 (Schedule A)) QHP's organizational structure is non-public confidential commercial information. Topic 2 requests testimony about the "reasons for QHP's acquisition of CoreRx, and the facts and circumstances surrounding that acquisition." (*Id.*) Topic 6 requests testimony about "the level of control and/or oversight QHP exercises over

Azurity." (*Id.* p. 8) Topic 7 requests the same testimony about QHP's control over CoreRx. (*Id.*) The Document Requests seek similar information. (*Id.* p. 7 (Schedule B)) Document Request 1 seeks "documents sufficient to show the ownership of QHP, Azurity and CoreRx." (*Id.*) Document Request 2 seeks documents "sufficient to show organizational structure of, and corporate relationship between and among QHP, Azurity, and CoreRx." (*Id.*)

All of these proposed deposition topics and document requests go straight to the heart of QHP's confidential research and development, or confidential commercial information. Under Federal Rule 45(d)(3)(B)(i), this alone is a sufficient reason for the Court to quash or modify the QHP Subpoena. In addition, all of the Topics and Document Requests that seek the organizational structure, corporate relationships, ownership, and agreements of Azurity, a party to the litigation in which the QHP Subpoena was issued, should have been directed to Azurity. The same information with respect to CoreRx should have been, and might well have been, obtained in the SDNY Lawsuit between CoreRx and Bion.

Bion has not demonstrated a need for the testimony and documents requested by the QHP Subpoena that justifies invading QHP's confidential commercial information. As was discussed in detail in Subsections II.C. and D. above, the factual record in the SDNY Lawsuit provided Bion with extensive evidentiary information related its collusion theory and failed to support that theory. At best, the QHP Subpoena is a fishing expedition that seeks to locate different information than that which Azurity and CoreRx, the parties that would have had to have been directly involved in any theoretical collusion, have already provided. The QHP Subpoena seeks confidential research, development, and/or commercial information from QHP that justifies this Court in quashing the QHP Subpoena.

V. CONCLUSION

The QHP Subpoena imposes an undue burden on QHP, which requires that the Court quash or modify the QHP Subpoena pursuant to Rule 45(d)(3)(A)(iv). In addition, the QHP Subpoena seeks confidential research, development, and/or commercial information which permits the Court to quash the QHP Subpoena pursuant to Rule 45(d)(3)(B)(i). For these reasons, QHP respectfully requests that the Court grant QHP's motion to quash the QHP Subpoena.

Respectfully submitted this 13th day of June, 2023.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that the foregoing Motion to Quash was served on the parties to this action by email and by depositing a copy of same in the United States mail, first class postage pre-paid, and addressed as follows:

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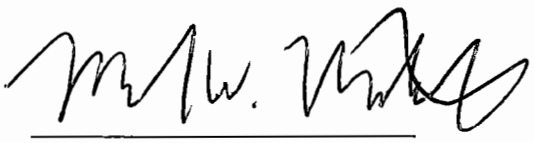
This the 13th day of June, 2023.



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